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Dockets Management Branch
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July 20, 2002

4168 '02 JUL 29 A9:33

Regarding FDA Docket No. 02N-0278

Proposed Section 307 (Prior Notice of Imported Food Shipments) - requires that prior notice of food shipments be given to FDA. The notice must include a description of the article, the manufacturer and shipper, the grower (if known), the country of origin, the country from which the article is shipped, and the anticipated port of entry. The Secretary, through FDA, must issue final regulations by December 12, 2003.

How will FDA enforce additional regulations and what is the penalty for non-compliance by a food shipper ?

It seems unlikely that FDA could possibly have enough resources to enforce such regulations. At present FDA and Customs are almost completely ineffective in preventing raw or frozen molluscan shellfish products exported by non-MOU nations from entering the United States and causing illness outbreaks. Dozens of shipments of molluscan shellfish enter the U.S. weekly, if not daily, from China and other countries that have not signed a memorandum-of-understanding (MOU) to implement their shellfish sanitation program in a manner that assures public health protection equivalent to that of the National Shellfish Sanitation Program (NSSP) of the United States. Such products are defined as adulterated under FDA regulations, they represent a hazard to the health of shellfish consumers, indeed they have caused documented illness outbreaks, and should be denied entry to the U.S. but they continue to stream into the U.S. food supply nearly unchecked.

The continuing failure to prevent the entry of tons of such molluscan shellfish products from non-MOU countries occurs despite FDA's own seafood HACCP regulations (21 CFR Parts 124 and 1240) adopted in December 1995. Said regulations clearly specify that shellfish that do not originate from an MOU country, or for which evidence cannot be supplied that prove the product was produced in a manner equivalent to the standards of the NSSP, are defined by those regulations as adulterated and will be denied entry. Yet tons of such shellfish from many such countries are routinely NOT being denied entry, even when FDA knows that the country of origin is a non-MOU country and/or when no credible evidence is produced that the shellfish were produced in accordance with the HACCP regulations adopted in 1995.

Apparently, FDA counsel is of the opinion that FDA's own HACCP regulations are so impotent that FDA cannot deny entry to such adulterated products. As a result, there is appears to be little effective effort to identify and interdict such potentially hazardous products and FDA apparently imposes no penalty on either the shellfish exporter or importer associated with adulterated shellfish product entering the United States.

FDA's strategy to curtail the distribution of shellfish from non-MOU countries seems to be to allow it into the country and then ask the various states' shellfish sanitation programs to embargo the product. FDA does this knowing full well that virtually all states' shellfish and enforcement programs are operating at the limit of their dwindling resources. In fact, FDA's most recent program evaluation report found one northeastern state's shellfish enforcement program element to be "not in substantial compliance" with the requirements of the NSSP, yet FDA continues to permit shellfish from non-MOU countries to enter the U.S. hoping that state and other neighboring port-of-entry states can embargo and destroy such adulterated product, creating additional work for those states' shellfish enforcement units.

In light of the fact that adulterated shellfish products from non-MOU countries are entering the U.S. and are known to be causing food borne illness outbreaks while little is being done by FDA to prevent the problem, except passing it along to the overburdened shellfish programs in port-of-entry states, the following question must be answered by FDA before it adopts more regulations aimed at controlling food imports - "Since FDA cannot enforce its existing regulations that apply only to seafood and molluscan shellfish imports, which make up but a small percentage of the foreign foods entering the U.S., how will the new proposed regulations, Section 307 (Prior Notice of Imported Food Shipments), which cover an even broader spectrum of food products, ever be enforced by FDA ?"

02N-0278
cc: Senator Charles Schumer
Senator Hillary Clinton
C. Smith-DeWaal, CSPi

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Concerned citizen

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